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5.0 - 510(k) Summary

Date Prepared: April 6, 2012

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6854
Device Name:	Synthes Variable Angle LCP Elbow System (Medial and Posterolateral Distal Humerus Plates)
Classification:	Classification: Class II, §888.3030, Single/multiple component metallic bone fixation appliances and accessories. Product Code: HRS, HWC
Predicate Device:	Synthes 3.5mm LCP Elbow System (K033995) Synthes Small Fragment System (K000684) Synthes 2.4 mm / 2.7 mm VA-LCP Forefoot /Midfoot System (K100776) Synthes 2.7/3.5mm VA-LCP Elbow System (K120070)
Device Description:	The Synthes Variable Angle LCP Elbow System contains posterolateral and medial plates intended to treat fractures of the distal humerus. The plates are used together in a two-plate, 90° construct and accept existing screws. New 2.7mm Metaphyseal Screws are also compatible with the System.
Intended Use:	The Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna in adults and adolescents (12-21) in which the growth plates have fused. Specifically, · Distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus. · Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.
Substantial Equivalence:	Both the subject Synthes Variable Angle Elbow System (Medial and Posterolateral Distal Humerus Plates) and predicate Synthes 3.5mm LCP Elbow System (K033995) and Synthes Small Fragment System (K000684) have similar indications, design characteristics, materials, and performance characteristics. Static and fatigue strength testing, as well as an engineering analysis, was completed for Medial and Posterolateral Distal Humerus Plates, demonstrating equal to or greater strength in comparison to the predicate devices and

	constructs. Additionally, mechanical testing for the 2.7mm Metaphyseal Screws demonstrated substantial equivalence in comparison to the existing 2.7mm VA Locking Screws (K100776).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 8 2012

Synthes
% Ms. Angela F. Lassandro
1301 Goshen Parkway
West Chester, PA 19380

Re: K120717
Trade/Device Name: Synthes Variable Angle LCP Elbow System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS, HWC
Dated: March 5, 2012
Received: March 12, 2012

Dear Ms. Lassandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120717

Device Name: Synthes Variable Angle LCP Elbow System

Indications for Use:

The Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna in adults and adolescents (12-21) in which the growth plates have fused. Specifically,

- Distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus.
- Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120717